

DOCKET NO. PRES06-00163
SERIAL NO. 09/556,143
PATENT

REMARKS

Claims 40-59 were pending in this application.

Claims 40-59 have been rejected.

Claims 40-59 remain pending in this application.

Reconsideration and full allowance of Claims 40-59 are respectfully requested.

I. OBJECTION TO OATH/DECLARATION

The Office Action objects to the originally-filed declaration. On February 15, 2008, the assignee of this application filed a renewed Petition Under 37 C.F.R. § 1.47(b) due to the inventor's unavailability or unwillingness to sign the Declaration. If granted, the renewed petition overcomes the objection to the declaration.

II. REJECTION UNDER 35 U.S.C. § 102

The Office Action rejects Claims 40-59 under 35 U.S.C. § 102(b) as being anticipated by March et al., "Safety of High-Energy Neodymium:YAG Laser Pulses in YAG Sclerostomy" ("*March*"). This rejection is respectfully traversed.

A prior art reference anticipates a claimed invention under 35 U.S.C. § 102 only if every element of the claimed invention is identically shown in that single reference, arranged as they are in the claims. (*MPEP* § 2131; *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (*Fed. Cir.* 1990)). Anticipation is only shown where each and every limitation of the claimed

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invention is found in a single prior art reference. (*MPEP* § 2131; *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985)).

To establish inherency, the burden is on the Patent Office to present evidence clearly showing that “the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” (*MPEP* § 2112). However, the fact that a “certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” (*MPEP* § 2112). The Patent Office must “provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows” from the teachings of cited reference. (*MPEP* § 2112).

Claims 40, 47, and 54 recite irradiating a sclera of an eye to “increase an effective working distance of a ciliary muscle of the eye.” Claims 40, 47, and 54 also recite “reducing a thickness of the sclera in the region of the ciliary body without forming an opening completely through the sclera.”

The Office Action’s assertions of inherency and anticipation are improper for at least three reasons:

- (1) the Office Action confuses the actual technique disclosed in *March* with the “prior art” techniques discussed in *March*;
- (2) the Office Action ignores the actual express purpose of *March*; and
- (3) the Office Action relies on a string of unsupported assumptions to assert that *March* inherently anticipates the claimed invention.

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First, the Office Action properly notes that *March* discusses how prior laser techniques failed to create a "complete scleral perforation or sclerostomy." (See *March*, Page 586, Right column). In contrast, *March* describes an improved laser technique that does create a complete scleral perforation or sclerostomy.

In rejecting the claims, the Office Action relies on the prior laser techniques discussed in *March* as anticipating "reducing a thickness of the sclera in the region of the ciliary body without forming an opening completely through the sclera." The Office Action relies on the improved laser technique disclosed in *March* as anticipating irradiating a sclera of an eye to "increase an effective working distance of a ciliary muscle of the eye."

This is clearly improper because the Office Action never shows that *March* discloses a laser technique that both (1) irradiates a region of an eye to increase an effective working distance of a ciliary muscle of the eye and (2) reduces a thickness of the sclera of the eye without forming an opening completely through the sclera.

The Office Action cannot assert that the prior laser techniques mentioned in *March* anticipate the claimed invention. *March* never actually describes those techniques. The Office Action therefore cannot possibly show that the prior laser techniques mentioned in *March* inherently increase an effective working distance of a ciliary muscle of the eye since virtually no information is provided about those prior techniques.

Moreover, the Office Action cannot assert that the actual laser technique used in *March* anticipates the claimed invention. The actual laser technique used in *March* forms a complete

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opening in the sclera, which contradicts the express language in Claims 40, 47, and 54.

Second, the actual express purpose of *March* is to form a complete scleral perforation or sclerostomy to produce a “drainage fistula” that lowers intraocular pressure. (*March*, Page 584, *Left column*). In other words, *March* is specifically directed at decreasing the internal pressure of the eye.

In order for the Office Action’s assertion of inherency to be correct, the Office Action has to show that forming a hole in the sclera of the eye to reduce pressure within the eye allows scleral expansion to occur, which then increases the effective working distance of the ciliary muscle of the eye. This is equivalent to arguing that poking a hole in a balloon would allow the balloon to expand. This is clearly an improper basis for inherency.

March is crystal clear – the actual laser technique used in *March* forms a fistula or passage completely through the scleral tissue of an eye to reduce pressure within the eye. There is no possible way the Office Action can assert that forming this fistula would cause scleral expansion that increases the effective working distance of the ciliary muscle of the eye. The only way the Office Action can assert that *March* inherently increases the effective working distance of the ciliary muscle is to ignore the fact that *March* is decreasing the internal pressure in the eye (which the prior Office Actions apparently do).

Third, the Office Action asserts that the December 15, 2006 Office Action contained an “exhaustive treatment” of the inherency issue, particularly on pages 2-4. However, page 2 is directed at showing how *March* removes a portion of the sclera near the ciliary body. The first half of page 3 is directed at showing the high level of knowledge in the relevant art.

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The actual discussion of how *March* inherently anticipates the claims begins in the middle of page 3, and the inherency argument is built on a series of three assumptions:

(i) removing tissue from the sclera would weaken the sclera, based (among other things) on unnamed "laws of physics;"

(ii) weakening the sclera requires that the sclera expand due to internal pressure; and

(iii) this expansion increases the effective working distance of the ciliary muscle.

Assumption (i) may or may not be correct. The Office Actions have never established that the drainage fistula formed in *March* would have a size and shape adequate to structurally weaken the sclera. For example, the Office Actions cite nothing in *March* showing that the amount of tissue removed to form the drainage fistula in *March* would structurally weaken the sclera by an adequate amount. It is clearly specified that inherency cannot be established by "probabilities" or "possibilities." (MPEP § 2112). The first assumption therefore fails to satisfy the requirements for establishing inherency.

Assumption (ii) is simply factually incorrect. Forming the drainage fistula as expressly taught by *March* is done to lower intraocular pressure. *March* therefore lowers internal pressure, which means that the scleral expansion assumed by the Examiner does not "necessarily flow" from the teachings of *March* as required for establishing inherency.

Assumption (iii) is based on both prior assumptions and also does not "necessarily flow" from the teachings of *March* as required to establish inherency. The Office Actions have never shown that the small drainage fistula formed in the eye according to *March* structurally weakens the

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sclera to the point where internal pressure can cause scleral expansion. The Office Actions have similarly never shown that the reduced pressure (which is created by the formation of the drainage fistula in *March*) would be able to cause scleral expansion.

It is clear here that the assumptions made in the inherency argument in the Office Actions fail to satisfy the requirements set out in MPEP § 2112. These assumptions are just that – assumptions. There has never been a showing that these assumptions must “necessarily flow” from the teachings of *March*, and at least one of these assumptions ignores and contradicts the express teachings of *March*.

A prior Advisory Action argued that the claims “make no reference to the changing pressure in the[] eye, and thus can be considered to encompass an increase of the working distance of the ciliary muscle relative to that which it would have at any given pressure.” (03/13/07 *Advisory Action*, Page 2). However, attention is drawn to the actual language of the claims, which recite “irradiating” (or “to irradiate”) the sclera of an eye in a particular region to “increase an effective working distance of a ciliary muscle of the eye.” It is irrelevant whether internal pressure in the eye varies. The only issue is whether *March* irradiates the sclera in a manner that (i) increases an effective working distance of a ciliary muscle of the eye and (ii) does not form an opening completely through the sclera.

Also, a prior Office Action asserted that since *March* uses pulsed lasers, the pulses prior to the “endpoint of treatment” anticipate the claims. (06/29/07 *Office Action*, Page 2, *Second paragraph*). Once again, this is an assertion that deals with “possibilities,” not facts that must

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"necessarily flow" from the teachings of *March*.

March merely notes that laser pulses could be between 130 and 135 millijoules in strength and 12 nanoseconds in length. (*March*, Page 584, Right column). The Office Action cites nothing in *March* showing that the amount of tissue removed in *March* during each pulse structurally weakens the sclera adequately to allow an increase in the effective working distance of the ciliary muscle. Moreover, the Office Action cites nothing in *March* showing the total duration for all of the pulses, so there is nothing establishing the length of time between the start and end of treatment (and it is during this time that the Patent Office must show an increase in the effective working distance of the ciliary muscle occurs, since it is only during this period when no opening is formed completely through the sclera). Again, the mere fact that something may result is not sufficient to establish inherency. (MPEP § 2112).

The Office Actions appear to be based on the assumption that the claims can be rejected as being inherently anticipated as long as any reference discloses any removal of scleral tissue in the region of the ciliary body and no complete opening is formed for any length of time. This is obviously the incorrect standard. To establish that *March* inherently anticipates the claims, the Examiner must instead show that *March* removes an appropriate amount of scleral tissue in an appropriate location to enable an increase in the effective working distance of the ciliary muscle to occur, while no complete opening is formed through the scleral tissue. The Examiner chose to reject the claims under § 102. The burden is therefore on the Examiner to show that each and every limitation in the claims is disclosed in *March*. The Examiner has not satisfied that burden.

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Accordingly, the assignee respectfully requests withdrawal of the § 102 rejection and full allowance of Claims 40-59

To the extent the Office Action implies an enablement rejection might be forthcoming, the assignee stands ready and willing to show that the claimed invention is enabled. The assignee also notes that one factor for enablement is the level of ordinary skill in the art, which the Patent Office has conveniently shown (on the record) to be quite high. (*See 12/15/06 Office Action, Page 3*). However, since no enablement rejection has been issued, no explanation will be given here regarding how the claims (some of which appear to have been examined at least seven different times) are now not enabled by the originally-filed disclosure.

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SUMMARY

The assignee respectfully submits that all pending claims are in condition for allowance and respectfully requests full allowance of all pending claims.


If any issue arises or if the Examiner has any suggestions for expediting allowance of this application, the assignee respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at wmunck@munckbutrus.com.

The Commissioner is hereby authorized to charge any fees connected with this communication (including any additional extension of time fees) or credit any overpayment to Deposit Account No. 50-0208.

Respectfully submitted,

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